EXHIBIT D

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO WAVE 5 AND ANY SUBSEQUENT WAVE CASES**	**Master File No. 2:12-MD-02327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

RULE 26 EXPERT REPORT OF DR. DANIEL ELLIOTT

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I. Background and Qualifications

I am an Associate Professor of Urology at Mayo Graduate School of Medicine in Rochester, Minnesota. I received an M.D. in 1993 from Loma Linda University School of Medicine in Loma Linda, California. Following graduation from medical school, I completed my surgical residency in Urology at the Mayo Graduate School of Medicine at the Mayo Clinic in 1999. I then completed a one-year advanced surgical fellowship at Baylor College of Medicine in Houston, Texas, in Neurourology, Urodynamics and Voiding Dysfunction. I then re-joined the faculty at the Mayo Clinic, where I have spent the last 15 years specializing in treating pelvic organ prolapse and urinary incontinence in women and urinary incontinence in men. I have published over 60 peer-reviewed articles and given over a hundred lectures, many of which relate to urinary incontinence and pelvic organ prolapse. A Mayo Clinic colleague and I were the first to perform robotic sacrocolpopexy surgery for the treatment of high-grade prolapse and to publish extensively on the subject. I am a frequent invited lecturer at medical and surgical conferences addressing pelvic organ prolapse and stress urinary incontinence and their evaluation, treatments, surgical options and management of complications. I have taken and passed the subspecialty credentialing process recently established by the combined boards of the American Board of Urology and American Board of Obstetrics and Gynecology in Female Pelvic Medicine and Reconstructive Surgery.

Attached, as Exhibit "A", to this report is a copy of my current curriculum vitae, which includes an up-to-date list of my publications, presentations, awards, and other academic activities.

II. Basis of Opinion

I have been asked to provide opinions regarding the subject of female stress urinary incontinence, its evaluation, treatments, surgical options and management of complications as well as to address the actions of Ethicon, Inc., Ethicon Women's Health and Urology, a Division of Ethicon, Inc., Gynecare and Johnson & Johnson (collectively referred to as Ethicon). The focus of my investigation for this report is on the Tension-Free Vaginal Tape-Obturator ("TVT- O") and, specifically, the characteristics of the product that make it defective or, in other words, that make the risks to the patient outweigh the benefits to the patients. My opinions are based on my personal knowledge, experience, and my investigation in this case. All of my opinions, and the basis of those opinions, are true and correct to the best of my knowledge and belief, including those related to scientific and medical issues, which I believe are true and correct to a reasonable degree of scientific and medical certainty. I do, however, reserve the right to supplement this report and my opinions in light of any additional material or information provided to me, including any reports submitted and/or any other discovery that is taken in this case. Furthermore, if called to testify, I would plan to use various demonstrative exhibits, animations, video recordings, and/or anatomic models to show the relevant anatomy and surgical procedures and to describe my opinions as set forth in this report.

My opinions and conclusions regarding the Tension-Free Vaginal Tape product, its surgical procedure, its impact on patients and surgical colleagues, as covered throughout this report, have not been derived in isolation or are the basis of solitary data and opinion; rather, my report has been formed and influenced by multiple sources, briefly summarized as follows. My independent clinical and laboratory mesh-specific research including clinical manuscripts pertaining to female SUI, female pelvic organ prolapse, including mesh-specific complications;

animal laboratory studies regarding the effects of polypropylene mesh and host foreign body response and inflammatory response; by advanced surgical fellowship training in Voiding Dysfunction and Neurourology, which is above and beyond the normal six-year urologic surgical training and my personal surgical, clinical, and research experience implanting synthetic mesh slings; my personal surgical, clinical, and research experience as a Female Pelvic Medicine and Reconstructive surgical specialist at a high volume tertiary center managing highly complicated SUI patients and the management of mesh-related complications, including the medical and surgical revisions, removal and treatment of synthetic mesh slings complications, including complications caused by the Ethicon TVT-O device; my attendance and participation at national and international Urological and Gynecological surgical meetings, including, but not limited to the International Pelvic Pain Society, International Continence Society meeting, Society of Female Urology and Urodynamics meeting, American Urologic Association meeting, Canadian Urological Association meeting, UCLA State of the Art Urology meeting, European Urological Association Subsection of Female Urology and Reconstructive Urology have also helped to form my opinions. I have prepared and have given lectures specifically focused on the complexities of treating female SUI and the management of complications associated with such treatments at national and international lectures including, but not limited to the International Continence Society meeting, Society of Female Urology and Urodynamics meeting, American Urologic Association meeting, Canadian Urological Association meeting, UCLA State of the Art Urology meeting, European Urological Association Subsection of Female Urology and Reconstructive Urology. I have had personal interactions and discussion with national and international urologic, gynecologic, urogynecologic and general surgery colleagues regarding the management of SUI in women,

manifestation of mesh-specific complications and the treatment of mesh-specific complications. As part of my interest in being as educated and as up-to-date and accurate as possible, I have reviewed the readily available medical literature pertaining to the treatment of SUI and the management of its complications from sources including but not limited to medical journals and the United States National Library of Medicine and the National Institute of Health.

I am a surgical journal editor and/or reviewer for 15 urologic and/or gynecologic journals (please see Curriculum Vitae for complete listing of journals) and was named Best Reviewer in Female Urology/Incontinence/Neurourology for two consecutive years (2012-2013) for the Journal of Urology. This is the highest honor awarded by the Editor of the Journal of Urology for excellence in manuscript review and preparation.

I have also performed a systematic review of internal Ethicon documents as they pertain to surgical mesh, TVT-O, the TVT-O procedure, expected SUI surgical results, expected SUI complications and rates of SUI complications, and marketing strategies designed for my surgical colleagues in urology, gynecology and urogynecology as well as for potential SUI patients. I have also reviewed the testimony of Ethicon employees. The materials I have reviewed and relied upon to form my opinion for this report are contained throughout the report and attached as Exhibit "B".

III. Summary of Opinions

A. Background on SUI and Treatments

B. The Polypropylene Mesh in the TVT-O Should Not Be Used in the Pelvic Floor

1. Polypropylene mesh in the TVT-O is not inert and degrades;

2. The TVT-O mesh is Heavyweight and Small Pore causing increased tissue response, chronic inflammatory response, contraction of the mesh, fibrotic bridging, folding and curling of the mesh, and scar plate formation;

3. Ethicon's cutting process made the mesh even more dangerous.

4. The TVT-O mesh tested positive for cytoxicity which can cause cell death and complications to women and, therefore, it should not be used in the pelvic floor;

5. The TVT-O design is flawed because it is too difficult to properly tension the TVT-O device due to lack of uniformity, and the device shrinks, ropes, curls and deforms making it impossible to tension

C. Ethicon Failed to Disclose and/or Downplayed Adverse Risks, Complications and Product Information in its Instructions for Use ("IFU")

D. Ethicon Failed to Test or Conduct Appropriate Studies Related to the TVT-O

E. Ethicon Failed to consider numerous known risks and hazards of the TVT-O while designing the product.

IV. Expert Opinions

A. Background on SUI and Treatments

1. Normal Anatomy vs. Stress Urinary Incontinence

Female stress urinary incontinence ("SUI"), also known as intrinsic sphincter deficiency (ISD), is a relatively common condition in which a woman leaks urine when her body experiences an increase in abdominal pressure, which in turn increases the pressure on the bladder. The abdominal pressure (A.K.A. "stress") is caused by a wide variety of activities including coughing, laughing, sneezing, jumping, bending over, picking something up, running, or any other sudden movement that increases pressure on the bladder.

In a woman, the urine leakage caused by SUI is due to factors like to weakening of the muscles that surround the urethra and/or a lack of fascial support for the urethra. The fascia below the urethra serves as a backboard to prevent the urethra from "falling down and funneling open." SUI is much more common in women than in men, largely because of pregnancy, childbirth, menopause and hysterectomies, to mention a few. Each of these conditions cause physical changes in the fascia used to support the urethra, which in turn results or contributes to

SUI. There are multiple fascias, or tissues, that support the urethra, including fascia located in the area of the pelvic floor and endopelvic fascia. In a woman with SUI, these fascia fail to provide sufficient support for the urethra, allowing the urethra to move downward when there is a sudden increase in pressure, such as that caused by a cough or a sneeze. When this happens, urine leaks out of the urethra.

SUI can have very serious effects on a woman's physical and mental health. It is not uncommon for women with SUI to stop participating in activities they once enjoyed, such as sports and other recreational activities or experience mental illness such as depression.

2. Alternative/Traditional SUI Treatment Options

Stress urinary incontinence affects approximately 15% to 35% of women in population-based studies [Abrams et al]. While surgical treatments are generally safe and highly effective, women with stress incontinence symptoms may wish to avoid or defer surgery for medical or personal reasons. Further, expert consensus groups recommend that non-surgical options should be offered as first-line therapy for incontinence [Hays et al].

3. Behavior modification & Pelvic Floor Therapy & Exercises

Simple lifestyle or behavioral modifications such as weight loss and/or avoidance of dietary irritants such as caffeine and nicotine are often the first line of treatment and therapy and may be the only treatment necessary. Also, pelvic floor muscle exercises (Kegel exercises) are used to strengthen the muscles surrounding the urethra so that urine is less likely to leak. These therapies require time, effort and commitment, but they do not have side effects and are often very effective.

Alternatively, pelvic floor electrical stimulation utilizes electrical current to strengthen the pelvic floor and to improve its function. Biofeedback is a treatment regimen performed under the care of a specialist and/or physical therapist. It is a safe and effective method of

increasing pelvic floor strength and has a role in helping women with mild stress incontinence. Biofeedback attempts to retrain patients on how to more appropriately use their pelvic floor muscles thereby improving their urine control. Consequently, the patient becomes more aware of her pelvic muscles and will be better able to identify and use them. Pelvic floor electrical stimulation combined with biofeedback may prove useful in that the electrical stimulation provides a passive contraction with increased awareness, via biofeedback, of pelvic muscle contractions.

4. Medication

There are several medications that have been studied for the potential treatment for SUI (Topical Estrogen, α-Adrenergic Agonists, Imipramine, Duloxetine, β-Adrenergic Antagonists, and β-Adrenergic Agonists). However, to date their benefit is minimal for SUI and is essentially limited to possibly benefiting overactive bladder.

5. Pessaries

Pessaries have been used for thousands of years to treat pelvic organ prolapse and SUI and, prior to the advent of successful surgical options; pessaries were essentially the only viable treatment for POP and SUI. Specifically, "continence pessaries" represent an alternative or complementary non-surgical approach to the treatment of stress incontinence. These devices work by providing a platform against which the urethra can compress during strenuous activity such as lifting or coughing. There are several studies describing the effectiveness of pessaries for treatment of stress incontinence but most of these studies are based on small samples of participants with short-term follow-up, which make their results questionable. Ultimately, however, due to inherent limitations of effectiveness and complications such as vaginal pain,

discharge, odor and necessity of routine medical care, most patients with SUI using pessaries discontinue using the pessary.

6. Surgery

Surgeons have spent hundreds of years trying to develop successful treatments for SUI. Over the course of time, several successful surgical techniques have been devised, but all of the treatments have the common component of reestablishing support for the urethra that has been weakened and damaged by childbirth, hysterectomy, obesity and age.

7. Marshall-Marchetti-Krantz & Burch Colposuspension:

In the 1940's, the Marshall-Marchetti-Krantz (MMK) procedure was developed. The MMK procedure is a surgery in which the surgeon secures the neck of the bladder—i.e., where the bladder meets the urethra—to the pubic bone with a series of sutures. The Burch colposuspension procedure is another procedure that was developed shortly after the MMK procedure. The Burch procedure is successful in treating urinary incontinence with success rates equivalent to mid-uretheral synthetic slings. The Burch procedure takes longer than a procedure to implant a synthetic mid-uretheral sling, however, the long-term complications with Burch related to chronic pain and dyspareunia are minimal when compare to mid-uretheral synthetic slings.

8. Pubovaginal Slings (Autologous/Cadaveric)

In the 1980's, a major advancement occurred with the introduction of a procedure known as the pubovaginal sling (PVS). The procedure uses harvested tissue from the tough abdominal wall tissue called abdominal fascia and then implants that tissue in the shape of a sling (hammock) around the neck of the bladder and up to the abdominal wall. Since the fascial tissue comes from the patient herself it is called "autologous" meaning tissue that comes from the same individual. The procedure rapidly rivaled the Burch colposuspension as the "gold

standard" for the treatment of SUI in women. With the advent of biologic and synthetic mesh-slings the number of PVS procedures initially decreased. However, with the increasing awareness among surgeons and patients regarding the complications (dyspareunia, life-altering pain, chronic sexual dysfunction, erosions and the others listed throughout this report) of vaginal synthetic mesh use, the PVS procedure has seen a significant resurgence. In some regions and practices around the nation, the PVS has become the mainstay of therapy. In my own personal practice, at a major tertiary referral medical center, I have abandoned essentially all synthetic mesh sling implantation due to the problems associated with complications, patients' fears, patients' refusal to have mesh inserted into their bodies and cost.

B. History of Synthetic Mesh Use in General Surgery

Abdominal and thoracic wall weaknesses, called hernias, exist due to weaknesses within the abdominal wall or thoracic wall due to conditions such as birth defects, surgery, and radiation effects. Traditional hernia repair surgery evolved using sutures (stitches) to bring the native tissue together. However, due to the inherent weaknesses of the tissues, failure was common and frequently resulted in significant pain and suffering for the patient. Therefore, in the 1950's, surgical meshes for hernia repairs were introduced. Subsequently, academic presentations, surgical reports and journal manuscripts began to describe mesh-related complications such as chronic pain, abdominal wall rigidity, mesh contraction, infection, fistula formation, chronic inflammatory process and recurrence.

An abundant amount of evidence in the medical literature and basic science data has been gathered over the past two decades that indicate that there is a strong and direct relationship between postoperative mesh complications and mesh design. Reducing mesh-related complications demands a thorough understanding and knowledge of the chemical,

physical and synthetic characteristics of meshes and how they react inside the human body. Based upon vast amounts of general surgery and basic science literature, there is a consensus that synthetic meshes that are low-weight, large-pore size, high porosity, monofilament, and capable of maintaining their elasticity under load will have the better results with fewer complications. Of all the mesh characteristics, mesh stiffness, porosity and the pore size of the mesh are of critical importance.

1. Synthetic Mesh Use in Pelvic Floor

Introduced in April 1997 as a treatment for female urinary stress incontinence, the ProteGen® sling was a synthetic polymer (polyester) mesh sling implant not a polypropylene mesh as is TVT. Surgeons implanted the ProteGen polyester sling underneath the urethra to provide support and to reduce SUI. Unfortunately, nearly immediately following Protogen's launch, a large number of patients began experiencing severe complications such as polyester mesh erosion through the vaginal wall, vaginal infections, vaginal discharge, vaginal bleeding, foul odor and dyspareunia. In January 1999, Boston Scientific Corporation, ProteGen's manufacturer, recalled the product due to the unusually high number of complications. In the December 1999 edition of *The Journal of Urology*, a group of respected urologists from across the United States reported their findings on those complications. These findings included a high rate of complications such as tissue erosion and urethral erosion among patients in whom the ProteGen sling was placed.

During the TVT-Retropubic's FDA submission process in the late 1990's, Ethicon used the ProteGen® sling as its predicate device despite the problems and ultimate recall discussed above. In 2003, Ethicon then used the TVT-Retropubic as its predicate device during the TVT-Obturator 510(k) submission process.

2. Mentor ObTape®

The ObTape® bladder sling was introduced in 2003 by the Mentor Corporation. The ObTape mesh sub-urethereal sling is a medical device, which was inserted through via a surgical procedure via the transobturator route for the treatment of female stress urinary incontinence.

ObTape bladder sling was used in around 36,000 women prior to its elimination from the medical device market in 2006 due to its high rate of complications. Although the Ob Tape mesh was presented as a permanent solution, a large number of women have experienced debilitating complications associated with their ObTape treatment. A 2007 study showed that over 20% of ObTape recipients experienced the extrusion of the sling through the vaginal walls [Siegal et al]. Other patients developed vaginal discharge, as well as pain during sexual intercourse as well as pelvic abscesses. Originally, it was assumed that problems with the ObTape sling stemmed from the mistakes of doctors. However, subsequent findings showed that the ObTape sling had an inherent design defect due to its use of overly dense and non-woven sling material. ObTape mesh erosions into the urethra can also result in the excretion of blood and urine. Initially, mesh erosion is typically treated with a cream prescribed by a doctor; but in many cases, the cream will not fix the mesh complication. In many mesh erosion instances, further surgery may be required to remove the mesh implant. Removal of the ObTape mesh sling may be successful in treating mesh erosion, but in some situations, even after multiple surgeries, there may be persisting complications due to mesh erosion.

3. TVT – Obturator

The Gynecare TVT Obturator device is intended to be used as a suburethral sling for treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The device is placed with a sterile, single-patient use

procedure kit consisting of two stainless steel, helical passers designed to deliver the TVT Obturator device, and a stainless steel winged guide designed to facilitate passage of the helical passers through the dissection tract.

a. TVT-O Device and Prolene Mesh Sling.

The TVT device is a sterile single-use device consisting of one piece of undyed or blue Prolene® polypropylene mesh (tape) approximately 1/2 x 18 inches (1.1 x 45 centimeters), covered by a plastic sheath overlapping in the middle. Plastic tube receptacles are attached at each end. The Prolene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in Prolene polypropylene nonabsorbable surgical suture. The mesh is approximately 0.027 inches (0.7 millimeters) thick. This material "when used as a suture" has been reported to be "non-reactive and to retain its strength indefinitely" in clinical use. According to the Ethicon IFU, the Prolene mesh is knitted by a process "that interlinks each fiber junction and that providing [sic] elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body."[1]

b. TVT Helical Passers.

The TVT helical passers are two stainless steel, curved wire tools with plastic handles that are preassembled as attachments to the mesh sling within the kit, and are designed to deliver the TVT Obturator device. The helical passers – one for placing the mesh sling on the left and one for placement on the right – are designed to ensure correct placement of the mesh sling. The attached plastic handles have the Gynecare logo and thumb imprint on them such that when the surgeon holds the handles properly, the logo faces the surgeon, who places his or her thumbs on the imprints.

[1] ETH.MESH.00353639, ETH.MESH.00015699 –00015706; ETH.MESH.00013506; ETH.MESH.00922443-00922445; ETH-00938; Walji Deposition p471-472; Robinson Deposition 3-14, p683-684; Kirkemo Deposition 4-18, p246-247, Ciarrocca Deposition 3-29, p264.

c. TVT Atraumatic Winged Guide

The TVT Atraumatic Winged Guide is a sterile component of the single-use kit. The instrument is intended to facilitate the placement of the helical passers into the two incisions the surgeon has made in the vaginal mucosa.

d. Surgical Technique

The surgeon makes a 1 cm midline incision in the vaginal mucosa starting 1 cm proximal to the urethral meatus. Using a "push-spread technique," the surgeon begins blunt dissection, typically using curved scissors. Dissection continues toward the "junction" between the body of the pubic bone and the inferior pubic ramus. When that "junction" is reached, the surgeon perforates the obturator membrane. The surgeon then inserts the Winged Guide into the dissected tract until it passes the inferior pubic ramus and enters the opening previously made in the obturator membrane. The surgeon inserts one of the helical passers and removes the Guide. The point of the Helical Passer should exit at a previously determined exit point. Connected to the Helical Passer, the plastic tube on the end of the mesh follows through the incision in the thigh. The surgeon pulls the plastic tube until the mesh tape appears, as which point the surgeon grasps the Passer tip firmly with a clamp and rotates the plastic handle to remove it from the assembly. The procedure is then repeated on the other side. The needles are then separated by cutting from the tape. The plastic sheaths that surround the tape are removed. By using patient feedback (e.g., coughing with a full bladder), appropriate tension on the sling is supposed to be determined taking care to avoid over-tensioning.

C. The Old Construction Heavy Weight/Small Pore Mechanically and Laser Cut Polypropylene Mesh in the TVT-O Should Not Be Used in the Pelvic Floor.

Because of the characteristics of the TVT-O discussed below and throughout this report, it is my opinion based on my training, experience, review of the scientific studies, Ethicon documents and depositions that TVT-O mesh should not be used in the pelvic floor. The old construction mechanically cut and laser cut mesh used in the TVT-O device should not be used in the pelvic floor because the risks of the device far outweigh the benefits of the device. The inadequacies of the mesh and the TVT-O lead to long term complications, including but not limited to, pain, acute and chronic pelvic pain, vaginal pain, permanent dyspareunia, injury and pain to partner during sexual intercourse, negative impact on sexual function, the risk of multiple pelvic erosions that can occur throughout one's lifetime, vaginal scarring, vagina anatomic distortion, inability to remove the device, permanent risks for erosions, the need for multiple surgical interventions that carry with them significant risks of morbidity, the development of worsening incontinence and urinary dysfunction including urinary urgency, urinary urge incontinence, urinary retention, suprapubic pain, suprapubic numbness, pain with lifting, pain with ambulation, and pain with sitting.

1. The mesh in the TVT-O is not inert and degrades

As polypropylene has been used in surgery for over 50 years as a suture material, Ethicon marketed the mesh in TVT-O as inert. However, many published studies and internal Ethicon studies and documents show that the mesh is not inert and does degrade.[2] In 1987,

[2] ETH. MESH.08315783 2012 + M CER: Reduction of the mass [of the implant] and the increase in the pore size of the mesh implant foreign body are seen to alter the inflammatory response which in turn is likely to alter tissue ingrowth... As the mass of the mesh implant is reduced and the pore size is increased the surface area exposed to the host is reduced, and the foreign body reaction to the implant is reduced."; ETH.MESH.02589033 - 02589079; ETH-80645 – 80651; Robinson Deposition 3-13, p 120; Hinoul Deposition 4-5, p165-170; Robinson Deposition 3-13, p129-130; Kirkemo Deposition 4-18, p138; 84 Klinge U, Klosterhalfen B, Muller M et al: Foreign body reaction to meshes used for the repair of abdominal wall hernias. Eur J Surg. 1999 Jul;165(7):665-73. Klinge U, Klosterhalfen B, Birkenhauer V: Impact of polymer pore size on the interface scar formation in a rat model. J. Surgical Research 103, 208-214 (2002). Klinge U, Klosterhalfen M, Muller A et al: Shrinking of polypropylene

Ethicon tested samples of explanted Prolene mesh made from the same material as the TVT-O mesh.[3] After 8 years of implantation, the testing showed that the mesh was severely cracked. In 1992, Ethicon completed a study where Prolene sutures were implanted in beagle dogs for up to seven years. These sutures were removed from the dogs and examined by Ethicon's own scientists, who found surface degradation in many of the samples after 7 years of implantation.[4] Ethicon scientist and corporate spokesperson, Thomas Barbolt, agreed that surface degradation can occur with the TVT mesh, and that this fact was confirmed by the Ethicon studies.[5] Because TVT-O uses the same polypropylene mesh as TVT, surface degradation can also occur with the TVT-O.

Further evidence that polypropylene mesh degrades over time was provided in 1998 by the publication of the Mary article, who studied the phenomenon of mesh degradation, and concluded the process of polypropylene cooling, where the polypropylene strand cools first on the inside and then on the outside can make the strand more susceptible to degradation on the outside.[6] In 2007, Costello et al., reported that polypropylene is more susceptible to degradation due to oxidation caused by inflammatory response.[7] Using Scanning Electron Microscopy (SEM), degradation could be seen in polypropylene in the form of cracks and peeling.

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mesh in vivo: an experiment study in dogs. European Journal of Surgery Volume 164, Issue 12, pages 965–969, December 1998.; Klosterhalfen B, Klinge W, Schumpelick V: Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair. Biomaterials. 1998 Dec;19(24):2235-46.; Klosterhalfen B, Klinge W, Hermanns B et al: Pathology of traditional surgical nets for hernia repair after long-term implantation in humans. [ABSTRACT] Chirugr 2000;71:43-51.; Klosterhalfen B, Junge K, Klinge W. The lightweight and large porous mesh concepts for hernia repair. Expert Rev Med Devices. 2005 Jan;2(1):103-17. Clave A, Yahi H, Hammou J, et al. Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 patients. Int Urogynecol J. 2010 Mar;21(3):261-70. Klinge et al The Ideal Mesh Klosterhalfen et al: Retrieval study at 623 human mesh explants made of polypropylene. Kwon Inflammatory Myofibroblastic tumor Birolini Mesh Cancer Sternschuss Post implantation alteration of polypropylene in humans ETH.MESH.02091873 -- abnormal chronic toxicity and doing nothing

[3] ETH.MESH.12831407.

[4] ETH.MESH.05453719.

[5] Deposition of Thomas Barbolt, January 8, 2014, pg 409:2-13; 516:21-517:4

[6] Mary, Celine, et. al. Comparison of In Vivo Behavior of Polyvinylidene Fluoride and Polypropylene Sutures used in Vascular Surgery

[7] Costello C., et al., "Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Mesh Explants from a Single Patient," Surgical Innovation , 2007, 143:168- 176).

Dr. Donald Ostergard, urogynecologist and founder of AUGS, created a presentation titled "Polypropylene is Not Inert in the Human Body" in which he described degradation of in vivo polypropylene.[8] Dr. Ostergard concluded that Prolene mesh degradation occurs by oxidation. He further concluded that a large surface area, such a piece of surgical mesh, in

contrast to a suture, incites more inflammation and results in more oxidation since more macrophages are present. These macrophages then secrete hydrogen peroxide and hypochlorous acid to oxidize the mesh, which can cause the mesh to become brittle and to crack. As discussed below, these changes cause complications to patients due to the increased inflammatory response.

In a 2010 article by Clave et al.,[9] 100 explants were analyzed. Results showed a greater than 20% rate of degradation from the implants. They concluded that "for transvaginal surgery, clinical experience indicates the use of low density, large pore implants knitted from a monofilament to facilitate tissue integration, and decrease the inflammatory response….not all types of PP implants degraded equally." It should be noted that the lead author, Henri Clave, holds an educational position for Ethicon Europe. In fact, Ethicon's scientists responded to that article, admitting that it was possible that the polymers may be subject to surface degradation free radicles and oxygen species in the human body, but that it did not know the clinical significance of these reactions.[10] Later, in 2013, the Wood study showed that polypropylene explanted from a patient showed significant oxidation of the material, and concluded that polypropylene will degrade in an oxidizing environment, such as a foreign body response in the human body.[11] Other authors and studies have demonstrated similar results with polypropylene

[8] "Polypropylene is Not Inert in the Human Body" Presentation by Donald R. Ostergard
[9] Clave, A., *Polypropylene as a Reinforcement in Pelvic Surgery is Not Inert: Comparative Analysis of 100 Explants*, I Urogynecol J 2010 21:261-270.
[10] ETH.MESH.07205369
[11] Wood, et. al. Materials characterization and histological analysis of explanted polypropylene, PTFE, and PET hernia meshes

in general.[12] In 2015, seven explants from sling devices, including the TVT, which is the same mesh as the TVT-O, were removed 4-7 years after implantation. Comparison of SEM images for explant samples with control pristine samples revealed extensive surface degradation and the formation of surface cracks in the samples, demonstrating the polypropylene fibers from mid-urethral slings are not inert over time.[13]

As polypropylene degrades, the inflammatory response increases and intensifies. The abraded fiber surface increases the surface area of the mesh, provides multiple areas that can effectively harbor bacteria, become brittle and creates a "barbed-wire" effect, all of which lead to an increased risk of an enhanced and chronic inflammatory response, as well as chronic infections due to bacterial proliferation at the mesh surface.[14]

The literature and internal Ethicon studies demonstrate that Ethicon's surgical polypropylene meshes oxidize, degrade, crack and peel in human tissue and become brittle. Dr. Iakovlev has also published numerous articles showing and explaining the degradation and surface cracking of polypropylene explants using histological and transmission electron microscopy approaches.[15]

Ethicon also knew this information before and at the time of launch of the TVT-O. There are Ethicon studies dating back as far as 1983 using test methods nearly identical to Dr. Iakovlev's showing in vivo degradation of the Prolene polypropylene material.[16] Ethicon

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from an individual patient. J Mater Sci: 24:1113-1122 (2013).

[12] Iakovlev, et al., Pathology of Explanted Transvaginal Meshes. Intl . Science Index Vol. 8 No. 9 (2014); Martin, MK Gupta, JM Page, F Yu, JM Davidson, SA Guelcher, CL Duvall. Synthesis of a Porous, Biocompatible Tissue Engineering Scaffold Selectively Degraded by Cell-Generated Reactive Oxygen Species. Biomaterials 35(12):3766-76, 2014; AE Hafeman, KJ Zienkiewicz, AL Zachman, HJ Sung, LB Nanney, JM Davidson, SA Guelcher. Characterization of degradation mechanisms of biodegradable lysine-derived aliphatic polyurethanes. Biomaterials 32(2):419-29, 2011.

[13] Tzartzeva, et al. In-depth nano-investigation of vaginal mesh and tape fiber explants in women. Abstract 366 (2015);

[14] [Mamy L, Letouzey V, Lavigne J et al: Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. Int Urogynecol J. 2011 Jan;22(1):47-52.]

[15] 15 Iakovlev V, Guelcher S, Bendavid R. In Vivo Degradation of Surgical Polypropylene Meshes: A Finding Overlooked for Decades. Virchows Archiv 2014, 463(1): 35; Iakovlev V, Guelcher S, Bendavid R. In Vivo Degradation of Surgical Polypropylene Meshes: A Finding Overlooked for Decades. Virchows Archiv 2014, 463(1):35.

[16] ETH.MESH.15955438

conducted additional studies in 1985 (dog study) and in 1987 (human explants); both showing in vivo degradation and cracking of the polypropylene materials.[17] In fact, Ethicon had its meshes reviewed by an outside consulting company who found that its meshes degrade and that the process starts immediately.[18] Yet, Ethicon never performed a study to determine the clinical significance of the degradation of its mesh.

It is my opinion, to a reasonable degree of medical and scientific certainty that polypropylene degrades in the human body causing the complications discussed throughout this report to women.

2. The TVT-O mesh is Heavyweight and Small Pore causing increased tissue response, chronic inflammatory response, contraction and shrinkage of the mesh, fibrotic bridging and scar plate formation, and folding and curling of the mesh.

Ethicon scientists have had data for over 16 years showing that heavyweight, small pore meshes are associated with excessive foreign body reaction, chronic inflammation, bridging fibrosis, scar plate formation, and consequential shrinkage of the mesh.[19] Further, Ethicon had data showing that the TVT-O mesh is heavyweight and has small pores.[20] Ethicon scientists expressed the need for decreasing complications rates from its heavyweight, small pore meshes through the development of lighter weight materials, which elicit a lower inflammatory response in the human body.[21] In fact, Ethicon has developed lighter weigh materials for use elsewhere in the human body, including the pelvic floor. However, today, Ethicon continues to

[17] ETH.MESH.00004755; ETH.MESH.11336474; ETH.MESH.13334286
[18] ETH.MESH.07192929
[19] ETH.MESH.05479411; Klinge U., Klosterhalfen B., Birkenhauer V., Junge K., Conze J., and Schumpelick V., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model; Cobb W, Kercher K, Heniford T. The Argument for Lightweight Polyropylene Mesh in Hernia Repair. Surgical Innovation. 2005; 12(1):T1-T7; Cobb, W., et al. Textile Analysis of Heavy Weight, Mid-Weight, and Light Weight Polypropylene Mesh in a Porcine Ventral Hernia Model. Journal of Surgical Research 136, 1-7 (2006); Klinge U, Klosterhalfen B, Muller M, Ottinger A, Schumpelick V. Shrinking of Polypropylene Mesh in vivo: An Experimental Study in Dogs. Eur J Surg. 1998: 164; 965-969; Klosterhalfen, B., Junge, K., Klinge, U.The lightweight and large porous mesh concept for hernia repair. Expert Rev. Med. Devices. 2005; 2(1)
[20] ETH.MESH.05479411, Cobb et. al., The Argument for Lightweight Polypropylene Mesh in Hernia Repair, Deposition of Joerg Holste, July 29, 2013 40:12-15, Deposition of Brigette Hellhammer MD., September 11, 2013 151:16-20, ETH.MESH.05479535
[21] ETH.MESH.01203957, Trial Testimony of Piet Hinoul, Batiste March 27, 2014 afternoon, 73:11-25

use the heavyweight, small pore Prolene mesh, originally developed in 1974 for use in hernia surgery, for its TVT-O device used for SUI.[22] This is true despite the fact that Ethicon scientists and others have demonstrated that the heavyweight, small-pore meshes have a greater inflammatory response and are related to increased rates of patient complications than lightweight large pore meshes regardless of where the mesh, is located in the human body.[23]

The implantation of the TVT-O mesh creates a foreign body reaction and a chronic inflammatory response that can lead to chronic pain in the patient. The body's foreign body response to the mesh can cause a severe and chronic inflammatory reaction leading to excessive scarring in and around the mesh and the degree of this reaction is directly related to the weight and pore size of the mesh device.[24] [25] [26] [27] Ethicon has known that clinical data have shown more chronic pain with heavyweight meshes such as the TVT-O mesh, than with lightweight, partially absorbable meshes. Ethicon's own medical director has stated that the presence of the foreign body, i.e. the TVT-O mesh, can be responsible for chronic pain syndrome in the patient.[28] In fact, one study has found that heavyweight meshes with small pores had to be explanted due to chronic pain more frequently than lightweight meshes with large pores.[29]

The foreign body reaction caused by the TVT-O mesh is chronic and this chronic inflammation and reaction can lead to mesh contraction and shrinkage.[30] Most studies show less shrinkage than heavyweight meshes, and pore size is one of the most important factors

[22] ETH.MESH.04941016, HMESH_ETH_02030355,
[23] Deposition of Joerg Holste, July 29, 2013 95:4-11
[24] Deposition of Piet Hinoul, April 4, 2012 99:99-99:25
[25] ETH.MESH.08315782
[26] Trial Testimony Piet Hinoul, March 27, 2014 afternoon, 27:10-17
[27] ETH.MESH.05916450
[28] ETH.MESH.01202101
[29] Klostherhalfen,B, Junge, K, Klinge, U, "The lightweight and large porous mesh concept for hernia repair," Expert Rev. Med. Devices, 2005 2(1)
[30] Deposition of Christophe Vailhe June 21, 2013 838:8-19

regarding mesh shrinkage.[31] Ethicon knew that all polypropylene meshes experience a 20-50% reduction in their initial size following implantation in the body.[32] Ethicon's medical director knew that the TVT-O mesh can shrink, and generally believed the TVT-O mesh would shrink approximately 30% post implantation.[33] The mesh contraction and shrinkage can increase the degree of foreign body reaction and mesh degradation, increasing the degree of pelvic pain and pelvic floor dysfunction such as sexual activity and urination, pain with sitting, and ambulation.[34]

A recent study has shown that mesh shrinkage is progressive and there is a linear evolution of the contraction rate over time, indicating that mesh contraction continues in the patient's body indefinitely into the future.[35] Vaginal mesh contraction can result in vaginal fibrosis, infection, chronic vaginal pain, chronic pelvic pain, vaginal shortening, vaginal narrowing, vaginal extrusion, adjacent organ erosion, and dyspareunia. Feiner and Maher evaluated 17 women with vaginal mesh contraction to demonstrate that the mesh caused the condition. The patients' presenting complaints included severe vaginal pain, dyspareunia, and focal tenderness over contracted portions of mesh on vaginal examination, mesh erosion, vaginal tightness, and vaginal shortening. The patients underwent surgical intervention with mobilization of mesh from underlying tissue, division of fixation arms of the central graft, and excision of contracted mesh. Fifteen of 17 (88%) patients reported a 'substantial reduction in vaginal pain following explantation, while none of 11 (64%) reported 'substantial' reduction in dyspareunia. However, despite Feiner's relative success with mesh explantation, the adverse

[31] ETH.MESH.02316781
[32] Cobb W, Kercher K, Heniford T. The Argument for Lightweight Polyropylene Mesh in Hernia Repair. Surgical Innovation. 200
[33] ETH.MESH.03910418
[34] De Tayrac, et. al. Garcia M, Ruiz V, Godoy A, et al: Differences in polypropylene shrinkage depending on mesh position in an experimental study. American Journal of Surgery Vol 193, Issue 4, April 2007, p538-542
[35] Mamy L, Letouzey V, Lavigne J et al: Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. Int Urogynecol J. 2011 Jan;22(1):47-52.;

effects of transvaginal mesh contraction caused permanent life-altering sequelae in 22-46% of patients in this study.[36] I personally see this type of permanent life-altering sequelae in my daily practice in patients I treat for severe complications related to mesh slings, including Ethicon's TVT-O device.

Polypropylene induces a rapid and acute inflammatory response and a strong scar formation. Heavyweight meshes with small pores such as the mesh in the TVT-O, induce an intense, chronic foreign body reaction with intensified bridging scar formation.[37] An increased foreign body reaction with a chronic inflammatory response and the forming of a rigid scar plate are the primary reasons for the shrinkage and contraction of meshes. Decreasing the weight of these meshes reduces both shrinkage and the inflammatory response. A pore size of greater than 1 mm is needed to prevent the fibrotic bridging and scar plate formation.[38] The mesh in the TVT-O has a pore size that is much less than 1mm after implantation.[39] The fact that the pore size of the TVT-O is not greater than 1mm in all directions prevents proper tissue integration, which can reasonably be expected to result in the development of a rigid scar plate, leading to, among other things, the potential for increased erosion, pain, nerve entrapment, and dyspareunia.

As early as 1998, internal Ethicon documents show that the construction and weight of the Prolene mesh utilized in the production of the TVT-O needed to be improved due to the fact

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[36] Feiner B, Maher C. Vaginal mesh contraction: definition, clinical presentation, and management. Obstet Gynecol. 2010 Feb;115(2 Pt 1):325-30.;
Foon R, Toozs-Hobson P, Latthe P. Adjuvant materials in anterior vaginal wall prolapse surgery: a systematic review of effectiveness and complications. Int Urogynecol J Pelvic Floor Dysfunct. 2008 Dec;19(12):1697-706.

[37] ETH.MESH.02316781

[38] ETH.MESH.01785259; ETH.MESH.02316781; ETH.MESH.02148431 Klosterhalfen B, Junge K, Klinge W. The lightweight and large porous mesh concepts for hernia repair. Expert Rev Med Devices. 2005 Jan;2(1):103-17; Batke deposition 08/01/012 113:3 to 114:3, 172:6 to 174:15, 118:10 to 120:25;Hellhammer deposition 09/12/13 403:18 to 404:9; 407:13-23; Holste depositions 07/29/13 51:3 to 53:6; Holste Deposition 12/14/12 89:20 to90:21; Semin Immunopathol (2011) 33:235–243 - a Scar net formation following large pore (~3 mm) and b scar plate formation following small-pore (~0.3 mm) mesh implantation; Arnaud deposition 9/25/13 756:9 to 757:8; ETH.MESH.03021946 T-Pro Stage Gate Meeting on August 25, 2008; ETH.MESH.02587926 When the Implant Worries the Body; ETH.MESH.01752532: Mesh Design Argumentation Issues; ETH.MESH.01785259 January 17, 2010 Email re; +M relaxation; ETH.MESH.04941016 Lightweight Mesh Development

[39] ETH.MESH.08315783;

that the mesh curled and folded under tension and would not return to its original shape, remaining curled.[40] Ethicon embarked on the "Prolene Mesh Improvement Project" to address these problems with the mesh. Ethicon ultimately changed the original, heavyweight 1974 mesh used for flat hernia repairs by (1) changing the construction of the mesh to prevent the mesh from curling up under tension, and (2) changing the size of the fiber used in the mesh from a 6 mil fiber to a 5 mil fiber, making the mesh lighter weight.41 Despite these improvements to the Prolene flat hernia mesh, Ethicon continues to use the original construction, heavier weight 6 mil Prolene mesh in the TVT-O product. This is true even though Ethicon documents show that mesh curls under tension, and that the mesh is known for its "bad curling quality."[42] Even though documents demonstrate that the initial long-term goal of the mesh improvement project was to replace the TVT-O mesh with the improved construction, lightweight mesh,[43] Ethicon did not use the improved material because using a different mesh would "obsolete the clinical data" they already had on the TVT product, which was a competitive advantage for the company.[44] An illustration of the TVT Prolene mesh curling after being placed under tension can be seen below.

[40] ETH.MESH.09264945
[41] ETH.MESH.10603246, HMESH_ETH_00782152
[42] ETH.MESH.02182839, HMESH_ETH_02030355
[43] ETH.MESH.09264884
[44] ETH.MESH.03911107

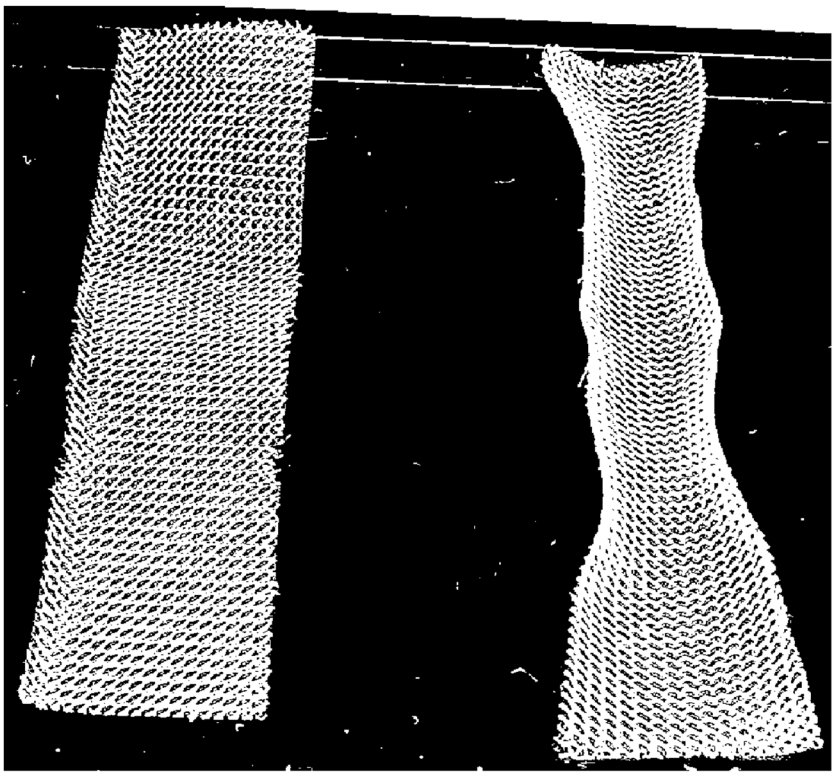
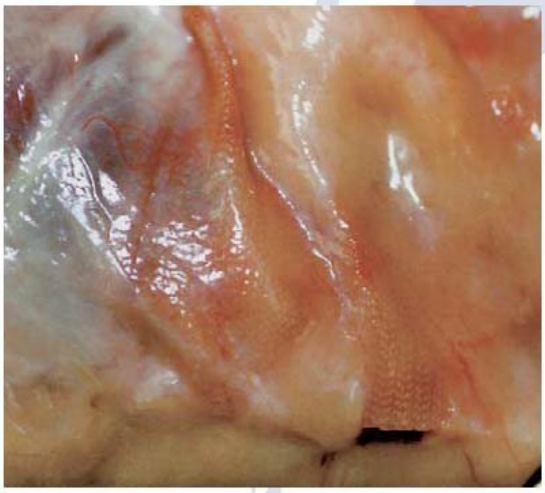


Figure 1 – Control mesh sample before and after the application of the force. A clear picture of mesh curling results.

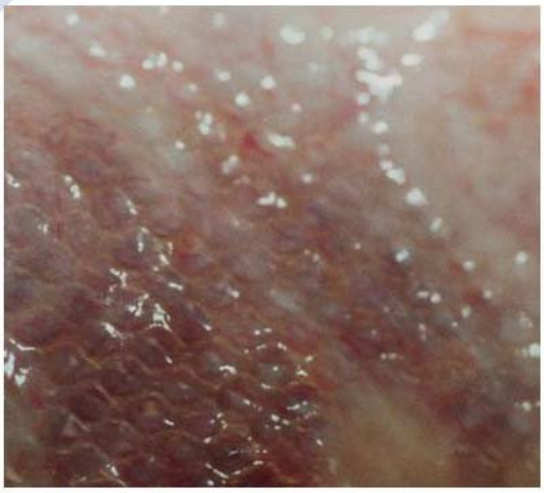
Ethicon is also aware that the heavyweight, small pore nature of the Prolene mesh makes it more likely than lightweight, large pore, partially absorbable mesh materials to "fold up" following implantation. This folding up of the mesh has also been referred to as the "potato chip" phenomena, which is caused by the increased inflammatory response to the increased weight and small pores of the current mesh.[45] Lightweight, large pore meshes tolerate compression much better than heavyweight Prolene mesh, which has pronounced edges and crumpling during tissue integration.[46] This folding of the mesh increases the amount of scar tissue formation and increases the likelihood of fibrotic bridging and scar plate formation of the mesh. In fact, in its 2004 product catalog, Ethicon advertised that its lighter weight, larger pore

[45] ETH.MESH.05918776
[46] ETH.MESH.05446129

Vypro mesh had 60% less foreign body material compared to the Prolene mesh, and was less susceptible to the development of folded mesh post-implantation.[47]



Traditional polypropylene mesh. 90 days post-implantation. Fold development (in-vivo study)



Lightweight VYPRO* II mesh. 90 days post-implantation. Fold-free incorporation (in-vivo study)

3. Ethicon's cutting process made the mesh even more dangerous.

For Ethicon's mesh that is mechanically cut, fraying is an inherent defect in the design of the device.[48] Stretching increases the probability of fraying, and when fraying occurs, the mesh narrows in places and particles break off and are lost from the mesh.[49] These defects in the mesh related to the mechanical cutting process lead to increased urinary retention, erosions, infections, extrusions and exposures of the mesh into vaginal tissues, and particles of the mesh migrating into surrounding vaginal tissues causing pain.

Ethicon performed testing on TVT mechanically cut mesh samples where the mesh was stretched to 50% elongation and then measured for particle loss. Ethicon performed this test because based on their experience, 50% elongation was the estimated amount of force that is

[47] Ethicon 2004 product catalog
[48] ETH.MESH.00541379
[49] ETH.MESH.00541379

placed on the mesh during implantation.[50] In fact, one of Ethicon's Senior Engineers, Gene Kammerer stated that "it is my experience, after viewing many surgical procedures and performing numerous procedures on cadavers myself, that the mesh stretches approximately 50% at the maximum."[51] Testing done by Ethicon in 2002 showed that after elongation, some test articles lost up to 18% of their weight from particle loss.[52] A study published in 2004 by Pariente found that the TVT sling lost 8.5% of its particles during testing, more than 5 other competing slings.[53] Another researcher found the TVT easily deforms when tensioned under the urethra, which results in fraying or tanged edges and thinning of the mesh.[54] In fact, fraying during elongation was a major complaint of customers,[55] and was critical to the quality of the TVT device.[56] Physicians told Ethicon that particle loss from implanted mesh can migrate through vaginal tissues and cause pain.[57] The reason for the laser cut mesh project was to eliminate or reduce the release of these particles.[58]

These issues which all existed with the TVT device were exacerbated with the TVT-O device because of the different path used to insert the device. In particular, physicians reported more difficulty removing the plastic sheath from the in-place mesh. This, in turn, led to increased tension on the mesh leading to more fraying, particle loss, roping and curling and decreased pore size. These can all lead to potential adverse events associated with tape tensioning, such as erosion, fibrotic bridging, retention, extrusion, pain, and nerve damage

During the development of the TVT-O, the inventor, Professor de Leval, used the "Babcock technique" to ensure that the tension on the mesh was proper, utilizing a Babcock

[50] ETH.MESH.01824104, ETH.MESH.00584811, ETH.MESH.00301874
[51] ETH.MESH.00584811; ETH.MESH.08334244
[52] ETH.MESH.04384185
[53] ETH.MESH.01221055, Pariente et.al., An independed biomechanical evaluation of commercially available suburetheral slings
[54] Moali et.al., Tensile properties of five commonly used mid-urethral slings relative to the TVT. Int Urgynecol J June 22, 2007
[55] ETH.MESH.10611169
[56] ETH.MESH.00301741
[57] ETH.MESH.05644164, ETH.MESH.03924557
[58] ETH.MESH.00301741

clamp to hold the mesh while he pulled off the sheath.[59] Ethicon refused to include the Babcock technique in the IFU or even to alert physicians that the TVT-O created unique sheath removal/tensioning issues.

Predictably, when Ethicon began marketing the TVT-O, complaints about sheath removal began to come in[60] and were widespread.[61] The Marketing Director and Co-Lead of the TVT-O Project noted her concerns that it was a worldwide ("WW") problem.[62] Ethicon refused to formally address the problem through changes to the IFU or Procedural steps (for example by adding the Babcock technique used by the inventor of TVT-O) leaving many physicians in the dark about why the sheath removal problems were occurring and what they could do about it.[63] Most importantly, without a proper fix, the tension-related defects and complications continued.

Ethicon continued to see problems with inconsistent tape width.[64] Doctors would report that the edges of the tape were crumbling, and that it got worse if the tape was stretched.[65] Ethicon had reports showing that the mechanically cut mesh was more likely to curl and rope which reduces the area of mesh to a localized point, increasing the pressure and potentially causing urinary retention.[66] Ethicon's Dan Lamont admitted that the fraying of the mesh was a

[59] ETH.MESH.00862727 (June 2, 2003 email from Dan Smith to others) ("Professor deLeval uses a Babcock clamp to place the TVT mesh tension free. We are not going to use this method at this time, however we discussed doing tests to ensure that the mesh is not damaged…. The reasons for use are as follows: 1st the mesh is maintained flat and cannot curl, 2nd the mesh in the 2-3 mm loop is maintained tension free during the adjustment phase of mesh insertion and 3rd the clamp is used as the guide and support as the plastic is removed to prevent overtensioning.").
[60] ETH.MESH.06884516 ("Sheath Removal problem: Dr. Jensen indicates that the issues began almost immediately when he converted to TVT-O (estimated late January/early February).").
[61] ETH.MESH.01815505 at 2 ("[T]he [sheath removal] issues experienced by Dr. Feagins are not unique to the Dallas market….they are being experienced by physicians all over the country and are creating serious challenges for the sales representatives.").
[62] ETH.MESH.01815505 at 8 ("From my perspective I strongly believe we have variability issues…. Having been in the OR with many surgeons the ease or difficulty of sheath removal can vary immensely…. Having spent time more time in the US this week this is a WW issue and not market specific.").
[63] ETH.MESH06881576 ("I hear what you are saying about introducing it in the procedural steps, however, what we include in the procedural steps has to reflect the IFU. Our hesitancy about doing this for launch was because we were not sure of any potential damage to the mesh caused by the babcock.").
[64] ETH.MESH.12002601
[65] ETH.MESH.02180833
[66] ETH.MESH.01822361

"defect" of the mesh.[67] Ethicon also had data showing that the increased roping or deconstruction of the mesh knit due to the narrowing of the mesh could result in erosion.[68]

In 2005, Ethicon tested laser cut mesh for the TVT and again performed a 50% elongation test of the material and compared that side by side with the mechanically cut mesh.[69] The testing showed that that the laser cut mesh substantially reduced the roping, curling, fraying and particle loss they were seeing with the mechanically cut mesh.[70] However, as discussed below, laser cutting of the mesh introduced new and different problems.

The roping and fraying of the mechanically cut mesh results in increased particle loss and frayed and sharp edges, increased inflammation, and increased and exacerbated infections which all result in erosions, extrusions and exposures of the mesh into the vaginal tissue, chronic pain, and dyspareunia. These problems, along with numerous other complications, are things I see on a daily basis in my clinical practice dealing with mesh complications, including Ethicon's TVT- O device. Internal Ethicon documents reflect that it was important to have a mesh that did not fray or have "spiky" or sharp edges in 1997 before the TVT product was even launched in the United States, when it was reported to Ethicon that a patient treated with Prolene had a vaginal erosion requiring trimming of the mesh.[71] The scientific data also showed that ideally, the Prolene mesh should have a smooth edge,[72] and that the mesh in the TVT should minimize abrasion.[73] Ethicon received multiple reports from patients of frayed mesh extruding through vaginal tissues causing pain both for women and their sexual partners.[74] The laser cut mesh created smooth or beaded edges in contract to the sharp, spike-like edges of the

[67] Lamont Depo. (September 11, 2013) at 15:16-16:10.
[68] ETH.MESH.06696593
[69] ETH.MESH.08334244-45
[70] ETH.MESH.00526473
[71] ETH.MESH.12006257
[72] ETH.MESH.09266457
[73] ETH.MESH.12009276
[74] ETH.MESH.02620914-02620917; ETH.MESH.02620964-02620968, 02621143-02621146, 02622276-02622279,

mechanically cut mesh,[75] which, all otter things being equal, could reduce the possibility of vaginal erosion. Only, not all else was equal.

In 2005, Ethicon introduced laser cut mesh which decreased the likelihood of fraying mesh and in turn, substantially decreased the likelihood of these adverse events caused by fraying, particle loss, roping, deformation and sharp edges; yet Ethicon continued to sell the mechanically cut mesh for the TVT-O despite laser cut mesh being a safer option from the point of view of over-tensioning defects and complications. However, the laser cut mesh created another set of problems. In part due to the hard beaded edge, the laser cut mesh had different mechanical properties as compared to the mechanically cut mesh. Specifically, the laser cut mesh was stiffer, less flexible, and less elastic than the mechanically cut mesh.[76] These essential mesh properties affect how a plastic mesh performs when being implanted in the pelvic floor and change how much force the surgeon should use when implanting the mesh and setting the appropriate tension. As previously discussed, the tension in an implanted mesh can lead to complications such as pain, erosion, and damage to tissues and organs. Ethicon never warned doctors that the new laser cut mesh had different mechanical properties than the mechanically cut mesh. Instead, Ethicon assured doctors that the laser cut mesh was identical to the mechanically cut mesh.

Despite the fact that Ethicon introduced the option of laser cut mesh for the TVT and TVT-O, it continued to offer the mechanically cut mesh for financial reasons. The primary motivator for continuing to sell the mechanically cut mesh was that they did not want to make obsolete the years of clinical data that were already available on the TVT.[77] In fact, Ethicon employees were reluctant to change the mesh at all because they wanted to continue to rely on

[75] ETH.MESH.09656790-09656795
[76] Deposition of David Robinson, MD, July 25, 2013 at 507:18-508:1 & 509:6-21
[77] ETH.MESH.03911107

the clinical data already established, most notably the Ulmsten/Nilsson series of clinical studies.[78] Ethicon instead chose to allow both meshes to "ski on the market" with the mechanically cut mesh being offered as the "Colonel's original recipe" in order to maximize the sales of the product, initially only offering the laser cut mesh to those customers who asked for it.[79]

As a result of all of the defects and problems with the mesh discussed above, the TVT-O device should not be implanted into the human body for use in the treatment of SUI. These defects and problems with the mesh lead to numerous injuries, including but not limited to pain, acute and chronic pelvic pain, vaginal pain, permanent dyspareunia, injury and pain to partner during sexual intercourse, negative impact on sexual function, the possibility of multiple pelvic erosions that can occur throughout one's lifetime, vaginal scarring, vagina anatomic distortion, inability to remove the device, permanent risks for erosions, need for multiple surgical interventions, development of worsening incontinence and urinary dysfunction including urinary urgency, urinary urge incontinence, urinary retention, suprapubic pain, suprapubic numbness, pain with lifting, pain with ambulation, and pain with sitting.

4. Ethicon's Prolene Mesh tested positive for Cytotoxicity

Cytotoxicity is the quality of being toxic to cells. If a woman's tissues or organs are exposed to a cytotoxic substance, the cells can undergo necrosis and die rapidly, or they can undergo a form of controlled "cell death," known as apoptosis.[80] It is my understanding that it is common for medical devices to be subjected to cytotoxicity testing before they are marketed to doctors and patients. In support of its application to market the TVT in the United States, Ethicon did not perform any controlled clinical studies to determine the cytotoxic potential of

[78] Deposition of Brigette Hellhammer, MD, September 11, 2013 120-121; Deposition of Axel Arnaud, MD., July 19, 2013 35-37.
[79] ETH.MESH.00526473, ETH.MESH.00687820
[80] About Apoptosis. Apoptosis Interest group, National Institute of Health, November 13, 2009

the TVT prior to marketing the device, but instead determined that the "long term clinical experience with PROLENE mesh indicated that Cytotoxicity testing would be sufficient to support the biocompatibility of this [mesh] component."[81] Regarding the biocompatibility of the TVT-O mesh in its 510(k), Ethicon then stated the mesh was the same as the TVT mesh and did not perform any additional testing. Prior to the marketing the TVT device, the Prolene mesh had primarily been used in abdominal hernia repair, and had never before been specifically indicated for use in vaginal tissues. As a result, Ethicon's conclusion that no new clinical or animal studies were needed to evaluate the cytotoxic potential of the TVT mesh is not based on sound science.

In fact, to this day, I am not aware of any long-term studies undertaken by Ethicon to determine whether or not the TVT and TVT-O mesh is clinically cytotoxic in women.[82] However, early clinical studies indicated that the TVT mesh did indeed have cytotoxic potential. Notably, the 2004 Wang study reported a defective healing rate of 2.2% in a series of 670 patients, and a persistent defective healing rate of 1%.[83] While this study was not published until 2004, Ethicon had been advised that Dr. Wang had experienced 25 erosions from the TVT mesh, which he suspected was due to the body's rejection of the Prolene mesh in 2002.[84]

The initial Cytotoxicity testing of the TVT prototype device was conducted in March of 1997, and tested all components of the device together for a period of 24 hours. The results of this test indicated the mesh was severely cytotoxic.[85] Ethicon's own Scotland lab performed follow-up testing, this time testing the needle, heat shrinking tube, sheath, and polypropylene mesh separately. In this test, the polypropylene mesh in the TVT again tested positive for

[81] ETH.MESH.08476210
[82] Dr. David Robinson deposition, September 11, 2013, 1101:24-1102:5
[83] Wang AC, et. al. A histologic and immunohistochemical analysis of defective vaginal tape healing after continence taping procedures: A prospective case-controlled pilot study. American Jorunal of Obstetrics
[84] ETH.MESH.03736989, ETH.MESH.00409674
[85] ETH.MESH.06851860 at ETH.MESH.06852121

marked cytotoxicity. Ethicon did a third and final test in July of 1997, which finally provided a non-cytotoxic result for the polypropylene mesh. Ethicon relied on the results of this final, July 1997 test in support of its application to market the TVT device, and did not report the two prior positive cytotoxic test results to the FDA, surgeons, or the public. Ethicon's own Worldwide Medical Director from 2005-2010 was not aware of these positive tests during his tenure.[86] Notably, even the 1997 ISO elution testing showed that the polypropylene mesh in the TVT was moderate to severely cytotoxic, while the ISO agarose diffusion testing showed the mesh was non-cytotoxic. Despite the positive ISO elution testing, and the two previous tests showing the mesh was Cytotoxic, Ethicon concluded that "the long history of safe clinical use of polypropylene as a mesh and suture products suggests strongly that the material is inherently biocompatible, and the potential Cytotoxicity observed is self-limiting and minimal when compared to the implantation procedure itself."[87] It is my opinion, based on my training, experience, review of the scientific literature and Ethicon's documents and depositions, that based on the 3 positive cytotoxic test results, that Ethicon should have conducted long-term studies to assess the Cytotoxic potential of the TVT-O mesh prior to marketing the device in women. This is particularly true in light of the fact that the Prolene mesh had never before been indicated specifically for use in vaginal tissues, and that there was only limited, short term data for 200 patients on a prototype device available at the time the device was first sold in the United States. In addition, the reports of 25 tape erosions from Dr. Wang in 2002 should have triggered an additional testing and assessment of the cytotoxic potential of the TVT and TVT-O mesh, but no additional cytotoxic testing was done as a result of these reports. I have seen the clinical effects of the cytotoxic potential of the TVT and TVT-O mesh in my practice. When I

[86] Dr, David Robinson deposition, September 11, 2013, 1094:19-1095:1.
[87] ETH.MESH.08476210

have removed Prolene TVT and TVT-O mesh from patients with mesh erosion, the tissue surrounding the mesh frequently shows evidence of necrosis and cell death. This type of necrosis is typically due to either: toxins, infections, trauma, or some combination of the three.

5. The TVT-O design is flawed because there is no way to properly tension the TVT-O device to lack of uniformity and it shrinks, ropes, curls and deforms making it too difficult to tension properly

Proper tensioning of the TVT-O device is critical to ensure that the device is successful in its intended use to cure stress urinary incontinence and to prevent complications. However, the design of the TVT-O device is flawed because Ethicon cannot properly determine and/or instruct surgeons on the proper placement of the device and, in fact, Ethicon provides contradictory instructions on tensioning in its instructions for use.

It is known that improper tensioning of the TVT and TVT-O devices can lead to failure of the procedure, urinary retention, and well as urinary obstruction.[88] The fact that the cough test was necessary to properly tension the mesh was noted by Dr. Ulmsten in his original 1996 publication on the TVT, as well as the co-inventor of the TVT, professor Nilsson, who noted that there was a 15% difference in success rates between patients treated with the TVT under local anesthesia with a cough test, and under general anesthesia, where no cough test was possible.[89] Despite being aware of this concern, Ethicon launched the TVT with an IFU that informed physicians that the procedure could be performed under general or local anesthesia, yet did not inform physicians that the success rate was much greater if performed under local anesthesia with a cough test. The TVT-O IFU repeated this flaw.

[88] ETH.MESH.05222687
[89] ETH.MESH.0404851

Too much tension on the mesh can also lead to vaginal or urethral erosions.[90] In 2001, Ethicon medical directors were working on a product to create a standardized approach for tensioning the TVT and which would avoid excessive tension on the mesh, but this product was never completed, and Ethicon never properly addressed how to instruct surgeons how to properly tension the mesh.

The IFU for the TVT-O provides insufficient and contradictory information on how to properly tension the TVT-O. In fact, Ethicon employees have acknowledged that the TVT has never truly been tension free, despite years of marketing it as such, and that they cannot accurately describe how to tension the mesh.[91] The IFU's Warnings and Precautions section cautions surgeons to "ensure that the tape is placed with no tension under the mid-urethra." The surgeon is instructed to "position the tape loosely e.g. without tension" in the mid-urethral position and to adjust the tape so that leakage is limited to a few drops of urine. The physician must put some kind of tension or force on the tape in order to limit the leakage.

The IFU's Adverse Reactions section says that over correcting, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction, yet the surgeon has been previously provided with five conflicting and confusing instructions to place the tape with (1) tension-free, (2) loosely, (3) without tension, and (5) to adjust the mesh until leakage is limited.[92] This leaves the physician with no clear, articulable standard on how to void the serious adverse reaction of urinary retention or urinary obstruction. As noted above, all of these concerns were further exacerbated by the difficulties in removing the plastic sheath for the TVT-O device. Since it is generally impossible to adjust the tensioning more than 24 hours after an operation as tissue ingrowth begins to occur, a re-operation surgery is generally

[90] ETH.MESH.05529653; ETH.MESH.0016113; ETH.MESH.05529274; ETH.MESH.04044797
[91] ETH.MESH.01784428; ETH.MESH..06861473
[92] TVT-O IFU.

required to correct this adverse event. Therefore, it is particularly important for patient safety to determine and describe the proper tensioning of the device as part of the product design. In addition, IFU is silent of the fact that over tensioning can cause other adverse reactions as well, including vaginal or urethral erosion.

Moreover, Ethicon failed to inform that physicians that the mesh could shrink from 30-50% once the TVT was placed, which would affect the final placement and tensioning of the mesh, and failed to account for shrinkage in determining tensioning for the TVT-O.[93] Ethicon also failed to account for the effects that roping, curling, narrowing, and deformation of the mesh could have on tensioning.

It is my opinion to a reasonable degree of medical certainty that Ethicon failed to develop and articulate clear and accurate instructions to surgeons on how to tension the mesh. It is also my opinion to a reasonable degree of medical certainty that Ethicon cannot develop and articulate clear and accurate instructions on how to properly tension the mesh as long as defects of heavyweight mesh shrinkage, roping, curling, narrowing, and deformation of the mesh exist as those defects create too many variations in the tensioning of the device to be overcome by instructions, no matter how well designed and articulated they may be.

6. The MSDS for the Prolene mesh states not to use with strong oxiders like peroxides which can be abundantly found in the vagina

The polypropylene mesh in the TVT and TVT-O is made from plastic pellets supplied by Sunoco, a petrochemical company. Included with these plastic pellets is a material safety data sheet, (MSDS) which is intended to provide those handling or working with the product

[93] Ethicon scientists determined polypropylene mesh would likely shrink after implantation, and used 30% as a rule of thumb for that shrinkage. ETH.MESH.03917375. Actual shrinkage rates vary based on the individual patient, type of mesh, and location of mesh in the body.

instructions and information on how to handle the substance in a safe matter. The MSDS for the TVT and TVT-O polypropylene states:

> Incompatibility
>
> The following materials are incompatible with this product: Strong oxidizers such as chlorine, peroxides, chromates, nitric acid, perchlorates, concentrated oxygen, sodium hypochlorite, calcium hypochlorite and permanganates. Chlorine; Nitric acid;[94]

While the plastic used to make the TVT-O mesh is also used in a number of other Ethicon products, including Prolene hernia mesh and Prolene sutures, this warning is particularly important as it applies to the TVT-O mesh, as the TVT-O mesh is intended to be placed in the vagina, which is a ready and natural source of peroxides, a strong oxidizer. Peroxides are regularly produced naturally by a woman's body. The Prolene hernia mesh is not intended to be placed in vagina, and the TVT-O mesh contains approximately 1,000 times more plastic material than a Prolene suture, so the clinical effects of oxidization would be markedly different between a suture and the TVT-O mesh.

This warning in the Prolene MSDS should have triggered an investigation into the effects that the naturally occurring oxidizers in the vaginal would have on the TVT-O mesh prior to Ethicon's marketing of the device, particularly with regard to oxidation and degradation of the mesh, as well as inflammation caused the presence of these naturally occurring substances in a woman's vagina. At the very least, Ethicon should have passed this warning along to surgeons and patients using the TVT-O mesh so they could make an informed choice about whether or not to use the device. However, no such warning regarding the TVT-O mesh's incompatibility with strong oxidizers has been communicated in the IFU, and Ethicon never did studies specifically examining the clinical effect of these natural oxidizers on the TVT-O mesh.

[94] Sunoco MSDS, 2003, 2005, 2009.

It is my opinion to a reasonable degree of medical certainty that Ethicon should have tested the clinical effects of the vaginal chemistry on the polypropylene used in the mesh and warned physicians about this incompatibility for use of the mesh in the vagina. Moreover, Ethicon should have informed physicians (and therefore patients) that the MSDS for its polypropylene noted a risk of carcinogenicity with the use of the plastic.

D. There are safer, feasible alternatives to the TVT-O Prolene mesh that would have reduced or eliminated many of the risks to patients in whom the TVT-O device has been implanted.

It is my opinion, to a reasonable degree of medical certainty, that using an alternative product like a suture product, as with the Burch procedure, or using a pubovaginal sling (autologous, cadaveric or xenograft) or an allograft sling, like Repliform, instead of the Prolene polypropylene mesh used in TVT-O, would have been safer, feasible alternatives that would have reduced the risk of the injuries suffered by women as a result of the defective TVT-O. A different suture material, a pubovaginal sling, an allograft sling or sutures used in an alternative design to the TVT-O, would reduce the risk of fibrotic bridging and mesh encapsulation, mesh contraction, mesh degradation, mesh hardening/rigidity, mesh curling/roping/fraying/deformation, mesh pore collapse/deformation at minimal stress, and chronic inflammation and chronic foreign body reaction of the TVT-O.

It is my further opinion to a reasonable degree of medical certainty that a shorter, lighter weight, larger pore mesh sling with less Prolene material (e.g., Ultrapro) would have been a safer, feasible alternative design and would have reduced the risk of the injuries suffered by women from the defective TVT-O. A lighter weight, larger pore mesh (e.g., Ultrapro) would reduce the risk of fibrotic bridging and mesh encapsulation, mesh contraction, mesh degradation, mesh hardening/rigidity, mesh curling/roping/fraying/deformation, mesh pore

collapse/deformation at minimal stress, and chronic inflammation and chronic foreign body reaction of the TVT-O.

E. Ethicon Failed to Disclose and/or downplayed Adverse Risks, Complications and Product Information in its Instructions for Use ("IFU") for the TVT-O.

Ethicon's Instructions for Use ("IFU") fails to disclose important safety and risk information to physicians thereby compromising the ability for all levels of surgeons to adequately and appropriately consent their patients prior to the implantation of the TVT-O device. The IFU serves as the main modality for information regarding surgery. The IFU is the one document that Ethicon knew all surgeons see prior to the implantation of the TVT-O device.[95] In addition, according to Ethicon's Medical Director Piet Hinoul, physicians should be allowed to rely on the safety information in the IFU standing alone.[96] For this reason and according to Ethicon's own Regulatory and Medical Affairs, all risks associated with a medical device must be included in the products' IFU.[97] This is true so that all physicians know the safety and risk information known to a company and related to a specific product. In this case, the IFU for the TVT-O only lists the following information in its Adverse Risks Section for the TVT-O:

> Adverse Reactions
>
> * Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
>
> Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
>
> * As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheaths initially covering the PROLENE mesh are designed to minimize the risk of contamination.

[95] Deposition of Dr. Richard Isenberg November 6, 2013 566:4-8
[96] Deposition of Dr. Piet Hinoul, January 14, 2014, 1207:18-1208:11
[97] Deposition of Catherine Beath, July 12, 2012, 592:7-11, Deposition of Dr. Marty Weisberg, August 9, 2013, 959:19-960:15

* Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.

The IFU for the TVT-O fails to disclose numerous adverse risks, safety information and warnings that are associated with the product, including, among others, the following: Death, pain, chronic pelvic pain, permanent dyspareunia, permanent sexual dysfunction, injury and pain to partner during sexual intercourse, negative impact on sexual function, vagina anatomic distortion, inability to remove the device, permanent risks for erosions, surgical interventions, development of worsening incontinence and urinary dysfunction. My review of internal documents and the depositions of Ethicon employees reveals that Ethicon was aware of these risks before or at the time the TVT-O was first marketed and sold.[98]

Additionally, Ethicon not only failed to disclose certain defects related to the product in the IFU, they downplayed several of the actual defects. In the TVT-O IFU, Ethicon stated, "Transient leg pain lasting 24-48 hours may occur and can usually be managed with mild analgesics." However, this warning is inconsistent with data available to Ethicon showing that the pain frequently extended beyond 48 hours and was often chronic. Additionally, defects related to the mesh that Ethicon failed to disclose in its IFU are as follows: roping, curling, fraying, particle loss, degradation, contraction and shrinkage, chronic foreign body reaction and decreased pore size. Ethicon also failed to disclose risks and information related to cytotoxicity and the MSDS discussed above.

Ethicon also failed to include warnings in its IFU related to the increased risk of mesh extrusion in women with prior vaginal surgeries, vaginal atrophy, vaginal injury, pre-existing pelvic pain disorders, immune-compromised and post-operative infection.[99] In addition, Ethicon failed to inform physicians that the TVT-O procedure performed under general

[98] Deposition of Piet Hinoul, June 27, 2013 552:2-9; Deposition of Catherine Beath, July 12, 2013; 608:13-20
[99] Deposition of Rick Isenberg, November 6, 2013 582:17-583:1, ETH.MESH.00159634 at 00159697; ETH.MESH.00203456.

anesthesia increases the risk of urinary retention, erosions and failure of the surgery. All of the above risks, safety and warning information was known to Ethicon prior to or around the time that the TVT- O was first marketed. Finally, Ethicon did not tell physicians that the TVT-O device would not work as well in smokers, young athletic women, older women or obese patients.[100] The failure to include this information deprived physicians of the information and prevented them from truly and fully being able to consent their patients prior implanting TVT-O devices or allow physicians to properly treat women with mesh complications.

Ethicon also downplays and misrepresents significant information in its IFU related to certain mesh properties. Despite the significant amount of data regarding mesh-related inflammatory response, the TVT-O IFU claims that implantation of Gynecare TVT-O mesh "elicits a minimal inflammatory reaction," which is "transient". This is not true as the inflammatory response is chronic according to my clinical experience with the mesh and the testimony of Ethicon Medical Directors David Robinson and Piet Hinoul and is extensively documented in Ethicon documents.[101]

In addition, Ethicon states in its IFU that the mesh is not subject to degradation, which is also inconsistent with Ethicon internal studies and documents and scientific studies examining mesh degradation. In short, Ethicon not only failed to disclose certain risks associated with the product, it downplayed or inaccurately portrayed issues related to the mesh in the IFU. Ethicon prevented physicians from being able to have an appropriate and accurate informed consent discussion with their patients by concealing and misrepresenting this type of information. As a result, numerous patients have suffered injuries from the TVT-O device that were not disclosed to them as potential adverse risks related to the TVT-O.

[100] ETH.MESH.00640394, DepositionofAaronKirkemo,January7,2014,556:4-19; 556:24-557:1; 557:5-558:21
[101] Deposition of Dr. David Robinson, September 11, 2013, 1087:7-1089:15; Deposition of Dr. Piet Hinoul, January 14, 2014, 1192:4-1199:12; ETH.MESH.02340504 TVT IFU; ETH.MESH.00339437-442 "5 Years of Proven Performance" Feb 2002

Interestingly, in May 2015, Ethicon issued a new IFU for the TVT-O which adds numerous new risks and warnings for the first time, including but not limited to acute and/or chronic pain, dyspareunia to patients and partners that may not resolve and that one or more revision surgeries maybe be necessary to treat adverse reactions.[102] As stated above, Ethicon had knowledge of these risks prior to the time the TVT-O was first marketed or sold.

F. Ethicon Failed To Conduct Appropriate Studies Related to the TVT-O

Ethicon has never conducted a long-term randomized controlled trial with safety as a primary endpoint.[103] There are also very few studies which have actually studied chronic, long-term pain with the TVT or TVT-O.[104] In addition, to my knowledge, with respect to studies performed by persons outside of Ethicon, very few are long term randomized controlled studies and none include a primary endpoint of safety.[105] There have also been recent studies that suggest that the studies assessing risks of synthetic mid-urethral slings to date are poor and that long term data or evidence lags behind shorter-term studies.[106]

Ethicon routinely relies and promotes its TVT-O product based on long-term data that originates from the original DeLeval data and studies. However, these studies lack significant data and fail to consider or inquire about many safety risks on the original patient cohort. In addition, Ethicon knew the DeLeval studies were uncontrolled, used different prototype devices and that the he had conducted his studies in violation of numerous criminal and civil laws.[107] The DeLeval data is also biased in that Dr. DeLeval had financial incentives to obtain certain

[102] TVT-O IFU, May, 2015
[103] Trial Testimony of Piet Hinoul in Linda Batiste Trial, 3-27-14 pm 57:9-12, 57:9-12
[104] Deposition of Dr. David Robinson, September 11, 2013, 978:7-14
[105] Deposition of David Robinson, 977:2-18
[106] Ford, et. al. Mid-urethral sling operations for stress urinary incontinence in women (review). The Cochrane Library, DOI: 10-1002/14651858.CD006375.pub3 (2015); Blaivas, et. al. Safety considerations for synthetic sling surgery. Nat. Rev. Urol. 18 August 2015, e-publication ahead of print.
[107] ETH.MESH.03934952

results with his studies and received numerous payments, consulting agreements and royalties related to the TVT-O and his involvement with Ethicon.[108]

G. Ethicon Failed to consider numerous known risks and hazards of the TVT-O in its design process.

As part of its design process, Ethicon is required to look at the potential risks of the implant.[109] According to Ethicon's Former Medical Director, there is a very formal process related to FMEAs, failure modes and risk analysis in determining different ways that things go wrong.[110] In making these determinations about risks, Ethicon relies on medical expertise from urologist like me to project what potential harms might result based on experience and literature.[111] According to Ethicon, a risk assessment is required to take into account all of the potential harms a product can cause once implanted.[112]

I have reviewed the relevant risk assessment documents created as part of the design of the mechanical-cut TVT, including the Preventia risk analysis performed by Medscand AB in 2000 and the updated Risk Assessment done in 2002.[113] Additionally, I have reviewed the relevant risk assessment documents created as part of the design of the TVT-O.[114] These risk assessments leave out or do not take into account numerous risks and complications related to the TVT-O, including roping, curling, deforming, fraying, particle loss, degradation, contraction and shrinkage, chronic foreign body reaction and decreased pore size due to its heavyweight and/or the fact that the device is impossible or difficult to remove. Based on testimony and internal documents I have reviewed and discussed above, Ethicon had knowledge of these risks

[108] ETH.MESH.15955249; ETH.MESH.15363068; ETH.MESH.12002262
[109] Deposition of Dr. Aaron Kirkemo, January 6, 2014, 36:15-38:16
[110] Deposition of Dr. Aaron Kirkemo, January 6, 2014, 36:15-38:16
[111] Deposition of Dr. Aaron Kirkemo, January 6, 2014, 36:15-38:16
[112] Deposition of Scott Ciarocca, March 29, 2012, 97:23-98:21
[113] ETH.MESH.01317508
[114] ETH.MESH.00259473 (TVT-O DDSA)

at the time the TVT-O was launched.[115] As a result, Ethicon should have taken these into account during the design of the TVT-O and should have designed out these defects or warned about them. Because Ethicon failed to do so, the risks of the TVT-O are too great, and outweigh the benefits of the product.

For the reasons set forth above, the old construction mesh as used in the TVT-O device should not be used in the pelvic floor when implanted in this manner. These design defects of the mesh and the TVT-O lead to long term complications, pain, acute and chronic pelvic pain, vaginal pain, permanent dyspareunia, injury and pain to partner during sexual intercourse, negative impact on sexual function, the possibility of multiple pelvic erosions that can occur throughout one's lifetime, vaginal scarring, vagina anatomic distortion, inability to remove the device, permanent risks for erosions, need for multiple surgical interventions, development of worsening incontinence and urinary dysfunction including urinary urgency, urinary urge incontinence, urinary retention, suprapubic pain, suprapubic numbness, pain with lifting, pain with ambulation, and pain with sitting.

V. Exhibits

My current curriculum vitae is attached as Exhibit "A".

All materials that have been available to me to consider in support of my finding and opinions are included above and listed below in Exhibit "B".

VI. Recent Testimony

I have testified as an expert at the following trial:

Coloplast A/S v. Generical Medical Devices; United States District Court – Western District of Washington at Tacoma Case No. C10-227BHS

[115] Deposition of Piet Hinoul, June 27, 2013 552:2-9; Deposition of Catherine Beath, July 12, 2013; 608:13-20

Linda Gross et al. v. Gynecare, et al.; Superior Court of New Jersey Law Division – Middlesex County Case No. MID-L-9131-08– Report & Deposition

Diane Bellew v. Ethicon et al.; United States District Court, Southern District of West Virginia Case No. 2:12-cv-22473 – Report, Deposition & Trial

Janice L. St. Cyr v. C.R. Bard, Inc. et al.; United States District Court, Southern District of West Virginia Case No. 2:14-cv-02313

Kathleen Stanbrough v. C.R. Bard, Inc. et al.; United States District Court, Southern District of West Virginia Case No. 2:14-cv-06937

Sheila Sutton v. C.R. Bard, Inc. et al.; United States District Court, Southern District of West Virginia Case No. 2:14-cv-00105

Pamela Ailey v Cook Medical, Inc., et al.; United States District Court, Southern District of West Virginia Case No. 2:13-CV-20496

Patricia L. Hammons v. Ethicon, Inc., et al.; Philadelphia County Court of Common Please Case No. 0003913 – Report & De Bene Esse

Dale Watkins et al. vs. Ethicon, Inc. et al.; Superior Court of New Jersey Law Division – Bergen County Case No. BER-L-13787-14 MCL – Report & Deposition

Mullins et al v. Ethicon, Inc., et al.; Southern District of West Virginia Charleston Division Case No. 2:12-cv-02952 – Report, Deposition & De Bene Esse

Betty Funderburke v. Ethicon, Inc., et al.; Southern District of West Virginia Charleston Division Case No. 2:12-cv-09957

Donna Loustaunau v. Ethicon, Inc., et al.; Southern District of West Virginia Charleston Division Case No. 2:12-cv-00666

Cynthia Nix v. Ethicon, Inc., et al.; Southern District of West Virginia Charleston Division Case No. 2:12-cv-01278

Wilson Wolfe, Elizabeth Blynn v. Ethicon, Inc., et al.; Southern District of West Virginia Charleston Division Case No. 2:12-cv-01286

Nancy Smallwood v. Ethicon, Inc., et al.; Southern District of West Virginia Charleston Division Case No. 2:12-cv-01662

Tamara Carter v. Ethicon, Inc., et al.; Southern District of West Virginia Charleston Division Case No. 2:12-cv-01661

Lola Rose v. Ethicon, Inc., et al.; Southern District of West Virginia Charleston Division Case No. 2:12-cv-01336

Judith Kowalski v. Ethicon, Inc., et al.; Southern District of West Virginia Charleston Division Case No. 2:12-cv-01323

Lisa Russell v. Ethicon, Inc., et al.; Southern District of West Virginia Charleston Division Case No. 2:12-cv-26652

Kathy Jones v. Ethicon, Inc., et al.; Southern District of West Virginia Charleston Division Case No. 2:12-cv-09517

Andrea Clinton v Mentor Worldwide LLC; USDC Eastern District of Missouri, Case No. 16-319

Julie Schalk v. Ethicon, Inc., et al.; Southern District of West Virginia Charleston Division Case No. 2:12-cv-04806

Tamika Griffin v. Ethicon, Inc., et al.; Southern District of West Virginia Charleston Division Case No. 2:12-cv-04331

IN RE: Mentor Corp. Obtape Transobturator Sling Products Liability Litigation, Case No. 4:08-md-02004-CDL USDC Middle Dist of GA

VII. Compensation

I am compensated for investigation, study and consultation in the case at the rate of $700.00 per hour.

05/22/17
DATE

DANIEL ELLIOTT, M.D.